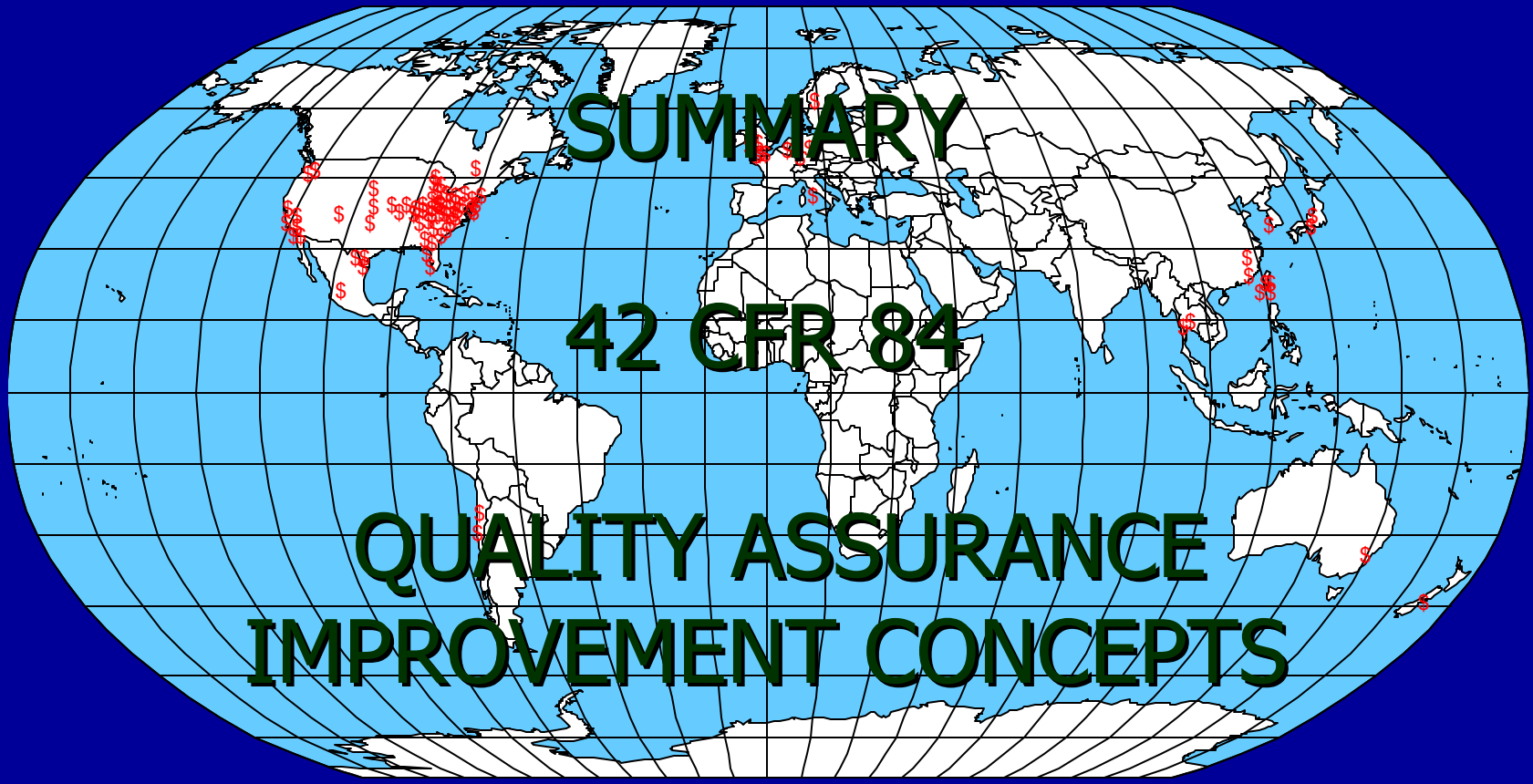
This presentation should not be considered a final statement of NIOSH policy or of any agency or individual who was involved. This information is intended for use in advancing knowledge needed to protect workers. Comments regarding this presentation may be submitted to the NIOSH Docket Office.



SUMMARY

42 CFR 84

QUALITY ASSURANCE IMPROVEMENT CONCEPTS

84 Manufacturing Sites in 18 Countries

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Looking Back

- 1972–1995 No New Respirator Standards
- 1995 Promulgation of 42 CFR 84
  - Modular Process
  - New Technical Standard for Particulate Filters
  - Beginning of Standards Development Activity
- 1996 to Present
  - CBRN SCBA
  - CBRN APR
  - CBRN Escape Respirators -Development
  - Quality Assurance - Development
  - Self-Contained Self Rescuers - Development

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Looking Back

- Public Discussion of QA Concepts
  - Stakeholder Meetings (May-Oct. 2000)
  - Private Sector Lab/Auditor Meetings (July 2000)
  - Public Meetings (August 2000)
- ISO 9001 2000 Established
- Establishment of the National Personal Protective Technology Laboratory (2002)
- New Personnel

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Public Health & Safety Impact

- Contemporary Manufacturing Processes
- Replace Outdated Quality Requirements
- Significant Nonconformance Rate
- Standards Development
  - Efficient Use of Resources
  - Outside Resources
  - Fees

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The Remedy

Objective	Mechanism
Consistency w/International Stds	Incorporate ISO 9000 Elements
Product Specific QA Requirements ▪ Quality Plans ▪ Sampling Procedure ▪ Quality Production Records	▪ Add In-Process Controls &/or more Stringent Sampling ▪ Incorporate First-Piece Inspections/Tests ▪ Implement Complaint Notification Program ▪ Retention of Quality Records for Life of Major Components
Validate Quality System prior to Approval	Manufacturing Site Approval & Audit

The Remedy

Objective	Mechanism
Audit Frequency Consistent w/QA Practice ▪ Semi-Annual Site Audits ▪ Annual Product Audits	Utilize Private Sector Resources ▪ Authorize RAB Accredited Auditors ▪ Authorized Accredited Labs
Recover & Retain Fees ▪ Approval Application Processing ▪ Records Maintenance ▪ Quality Activities Fees ▪ Retain fees to Enhance Standards Development Activities & Approval Processing	▪ Recover costs for Approval Processing Related Activities ▪ Recover costs for Maintenance of Approval Records & Management of Electronic System ▪ Recover costs for Manufacturing Site & Product Audits and Compliance Investigations

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The Remedy

Objective	Mechanism
Label Adequacy for Air-Purifying Respirators ▪ Eliminate Complexity & Size ▪ Provide User with Necessary Use Information	Proposed New Format ▪ Manufacturer & NIOSH Phone # ▪ Emphasis on Caution for Compliance with OSHA & MSHA on Respirator Usage ▪ Stipulate Cautions, Limitations, & Restrictions

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New and Improved

- The module development process
  - QA Module is relatively mature
  - Hybrid process
  - Periodic posting of concepts
  - Greater opportunity to interact

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Update

Objective	Mechanism	New
Consistency w/International Stds	Incorporate ISO 9000 Elements	Incorporate ISO 9001: 2000
Product Specific QA Requirements ▪ Quality Plans ▪ Sampling Procedure ▪ Quality Production Records	▪Add In-Process Controls ▪More Stringent Sampling ▪Incorporate First-Piece Inspections/Tests ▪ Implement Complaint Notification Program ▪ Retention of Quality Records for Life of Major Components	Through ISO 9001 Options created Limited implementation Retained Retained

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Update

Objective	Mechanism	New
Validate Quality System prior to Approval	Manufacturing Site Approval & Audit	Retained
Audit Frequency Consistent w/QA Practice ▪ Semi-Annual Site Audits ▪ Annual Product Audits	Utilize Private Sector Resources ▪ Authorize RAB Accredited Auditors ▪ Authorized Accredited Labs	Retained Utilize RAB auditors (demo by contract) Retained

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Update

Objective	Mechanism	New
Recover & Retain Fees ▪ Approval Application Processing ▪ Records Maintenance ▪ Quality Activities Fees ▪ Retain fees to Enhance Standards Development Activities & Approval Processing	▪Recover costs for Approval Processing Related Activities ▪ Recover costs for Maintenance of Approval Records & Management of Electronic System ▪ Recover costs for Manufacturing Site & Product Audits and Compliance Investigations	Retained Retained Retained

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Update

Objective	Mechanism	New
Label Adequacy for Air-Purifying Respirators ▪ Eliminate Complexity & Size ▪ Provide User with Necessary Use Information	Proposed New Format ▪ Manufacturer & NIOSH Phone # ▪ Emphasis on Caution for Compliance with OSHA & MSHA on Respirator Usage ▪ Stipulate Cautions, Limitations, & Restrictions	Under consideration - Comments?

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Opportunities to Improve

- Public Dialogue Facilitates National Acceptance/Familiarity
- Quality Standards Substantially Improved
- NPPTL & Fee Retention Provides Effective Implementation

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Implementation Issues

- Establish an Infrastructure to Implement Use of Private Sector Resources
- Completion of an Economic Analysis
- Administrative Funding Mechanism (Completed)

Schedule

- QA Concepts Being Revised
- Public Discussion of Concept Updates (June)
- Posting of Updated Concept (June)
- Concept Docket Closes (July)
- Public Meeting (September/October)
- Notice of Proposed Rule Making (December/January)